REMARKS

Amendment summary

Claims 17-19 and 39-41 are canceled.

Upon entry of this Amendment, Claims 1-16, 20-35, 37-38, and 42-56 will be pending.

No new matter is added by this Amendment, and Applicants respectfully submit that entry of this Amendment is proper.

Status of the claims

As a preliminary matter, the Examiner maintains the Restriction Requirement previously set forth, citing Konno et al. (Biomaterials, 2001,22, 1883-1889) (hereinafter "Konno") for support. Claims 17-19 and 39-41 have been rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. In addition, Claims 17-19 and 39-41 have been rejected under 35 U.S.C. § 112 as allegedly not being enabled by the present specification. Claims 1-14, 28, and 30 7-38 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Konno. Finally, Claims 15-16, 20-27, and 42-44 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Konno in view of Lobb et al. (J. Am. Chem. Soc., 2001,123, 7913-7914) (hereinafter "Lobb") further evidenced by Coessens (Prog. Polym. Sci., 2001, 26, 337-377).

Response to Restriction Requirement

Applicants gratefully acknowledge the Examiner's indication that Applicants' previous arguments with respect to the Restriction Requirement were persuasive. However, in view of the Examiner's new Restriction Requirement, Applicants again respectfully submit that that Groups I and II do not lack unity.

Specifically, Applicants respectfully submit that Konno discloses random copolymers, rather than the block copolymers of the present claims. Therefore, contrary to the position set forth in the Office Action, Konno does not break the unity of Claims 1-16, 20-35, 37-38, and 42-56.

Applicants submit herewith a Declaration under 35 U.S.C. § 1.132 by Dr. Andrew Lennard Lewis, the named inventor of the present application. In Paragraph No. 2 of the Declaration, Dr. Lewis describes that Konno discloses copolymers formed from a zwitterionic monomer and a hydrophobic monomer. As Dr. Lewis describes, Konno discloses that the monomers are polymerized to form random copolymers (see Paragraph Nos. 2-3 of the Declaration). Dr. Lewis also continues and explains how Konno does not disclose block copolymers.

Accordingly, Applicants respectfully submit that the special technical feature defined in Groups I and II, namely that the polymer is a block copolymer, does provide a contribution over the prior art, and that Konno does not break the unity of Claims 1-16, 20-35, 37-38, and 42-56. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the Restriction Requirement.

Response to rejections based on 35 U.S.C. § 112

Claims 17-19 and 39-41 have been rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. In addition, Claims 17-19 and 39-41 have been rejected under 35 U.S.C. § 112 as allegedly not being enabled by the present specification.

Applicants respectfully disagree with the positions set forth in the Office Action. However, in the interest of advancing prosecution, Applicants have canceled Claims 17-19 and 39-41.

Accordingly, Applicants respectfully submit that the rejections based on 35 U.S.C. § 112 have been rendered moot, and respectfully request the withdrawal of these rejections.

Response to rejections based on Konno

Claims 1-14, 28, and 30 7-38 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Konno. In addition, Claims 15-16, 20-27, and 42-44 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Konno in view of Lobb, further evidenced by Coessens.

Applicants respectfully submit that Konno does not anticipate or render obvious the presently claimed invention, neither alone nor in combination with Lobb or Coessens.

Independent Claim 1 recites an aqueous composition comprising an amphiphilic block copolymer having a hydrophilic block and a hydrophobic block, dispersed in the solution, and a biologically active compound associated with the polymer, wherein the hydrophilic block has pendant zwitterionic groups.

Applicants respectfully submit that Konno does not disclose a block copolymer. With respect to the known understanding of block copolymers and random copolymers, Applicants respectfully submit that the following description may be helpful to the Examiner.

It is known in the art that each block of a block copolymer must comprise a plurality of monomer units, and that a single monomer unit does not constitute a block. A block copolymer must be formed by a process involving separate steps of polymerising the respective blocks to

ensure that the constituents of one block are restricted to the desired components, and the constituents of the other block(s) are formed of the desired components.

Accordingly, a block copolymer is distinct from a random copolymer, which is produced by polymerising in the same reaction step two or more monomers. Thus, during the polymerisation of a random copolymer, both monomers will react to form part of the growing polymer chain. The arrangement of units in a random copolymer derived from two or more copolymerised monomers will depend upon the relative concentrations of the monomers. Overall the polymer composition may be defined by reference to the ratios (either by mole or by weight) of the monomer units in the product polymer. Usually, where the monomers polymerise optimally (i.e. approach 100% yield of polymer), the polymer composition is the same as the starting monomer composition.

A block copolymer may also be defined by reference to the relative ratios (again by mole or by weight) of the monomers used to form the individual blocks. Again, where there is an optimal yield of product polymer, the block copolymer ratio will be the same as the ratio of the amounts of monomers used to form the respective blocks.

Applicants respectfully submit that Konno does not anticipate or render obvious the presently claimed invention, which recites block copolymers, because Konno discloses a random copolymer. As explained in the attached Declaration by Dr. Lewis, Konno does not specifically describe the polymerisation process therein. However, he does refer to a conventional radical polymerisation process. This would be understood by a person having ordinary skill in the art to mean a random copolymerisation process. Had Konno been describing a block copolymer, then there would inevitably have been an extended description of the nature of the blocks, and likely

the polymerisation process, which is not considered "conventional." All of Konno's disclosure is consistent with the polymerisation being random.

Dr. Lewis also explains in the Declaration that Konno refers back to earlier publications describing the polymerisation method. In the document directly cross-referenced in Konno, there is no specific description of the polymerisation process. Instead there is reference back to a yet earlier publication, Ueda et al., from 1992, which does describe the conventional, random copolymerisation process.

Dr. Lewis also refers to later work conducted by this same group (headed by Professor Ishihara), published in Yusa et al. in 2005, where the properties of random copolymers and block copolymers of MPC with butylmethacrylate, are compared with one another and are described as solubilising hydrophobic therapeutic actives, such as taxol. The properties of the block copolymers, such as those recited in the present claims, are very different to those of the random copolymers of Konno and earlier prior art by this group. Accordingly, Dr. Lewis notes that the data therein provides further support for the surprising results disclosed in the present specification.

Accordingly, Applicants respectfully submit that Konno does not anticipate or render obvious the presently claimed invention because Konno does not disclose or suggest the presently recited block copolymer.

Applicants further respectfully submit that neither Lobb nor Coessens cures the above deficiency within Konno.

With respect to Lobb, Applicants respectfully submit that there is no reason to combine the teachings of Lobb with Konno in a manner that would render obvious the presently claimed invention. Specifically, Lobb does not teach that MPC block copolymers could be useful in

place of the random copolymers disclosed within Konno. In Konno, the (random) copolymers of MPC and butylmethacrylate are not being used as drug delivery vehicles themselves. Instead, the polylactic acid nanoparticles act as the drug delivery device, while the MPC/butylmethacrylate copolymer is merely provided as a coating to improve the biocompatibility of the nanoparticles. At Section 3.2 in Konno., the authors explain that the fluorescent probe being investigated (a hydrophobic material) permeates through the MPC polymer layer to be immobilised on the PLA particles. Thus, it is suggested that the polymer layer itself is not intended to control the release of the hydrophobic active, but only to allow the fluorescent hydrophobic material to become absorbed on the underlying PLA nanoparticles. The objective of the polymer is to affect the protein absorption on the PLA nanoparticles. This is determined in Konno by determining the adsorption of bovine serum albumin (BSA). Thus, the objective behind using the polymer in Konno is to have no effect on hydrophobic material which is to be absorbed onto the PLA nanoparticle, but only to have an effect on the interaction with protein and cell adhesion.

Applicants respectfully submit that there is nothing in Lobb to suggest that the block copolymers described therein would be used for associating with the block copolymer in an aqueous composition.

With regard to the Examiner's reliance on Coessens, Applicants respectfully submit that Coessens does not remedy the deficiencies described above.

In view of the above, Applicants respectfully submit that the presently claimed invention is not anticipated by or rendered obvious by Konno, either alone or in view of Lobb and Coessens.

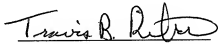
Applicants therefore respectfully request the reconsideration and withdrawal of these §§ 102 and 103 rejections.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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